

## Viking Therapeutics (VKTX - \$ 5.12)

### VK2809 Phase II Clinical Trial IND Application Submitted With Patient Enrollment to Start by Year End

This morning, VKTX announced the submission of an IND application to the FDA for conducting a VK2809 in hypercholesterolemia and fatty liver disease Phase II study.

- Details.** The Phase II study is a randomized, double-blind, parallel group, placebo-controlled trial designed to evaluate the efficacy, safety and tolerability of VK2809 in ~100 patients with elevated LDL cholesterol (>130) and fatty liver (min. 10%) disease. The study will evaluate three doses VK2809 vs. placebo. Patients are expected to receive VK2809 once-daily for 12 weeks with four weeks post-treatment follow-up. Eligible patients will have at least three NCEP ATP III guideline risk factors. Biopsy will be conducted in ~25% of patients to provide more insights. The primary endpoint is to evaluate the effect of VK2809 treatment on LDL-C after 12 weeks vs. placebo. Secondary and exploratory endpoints include changes in liver fat content, triglycerides, and inflammatory markers. We anticipate the study could start to enroll patients in mid-December 2015 with completion expected in 2H16 and top-line results potentially available in 1H17.
- Implications.** We view today's news as positive for VKTX share value since major clinical POC results of one of VKTX's leading assets could be just a few quarters away. This is due to the substantial investor interests in the clinical advancement of VK2809 in hypercholesterolemia and fatty liver disease; the drug's novel mechanism of action (as a thyroid-agonist); and its prior encouraging pre-clinical and clinical data, such as significant reduction of fasting triglyceride. Given that nearly half of patients suffering from higher LDL also have fatty liver disorders, VK2809 has a significant opportunity since most currently marketed drugs cannot address both indications simultaneously. As such, VK2809 could have potential for treating early stage NASH, in our opinion.
- Action.** We are reiterating our Buy rating and \$20 target price based on peer comparable, probability adjusted DCF and sum-of-the-parts analyses. Outcome of the POC clinical studies of the two leading assets could be available over the next 4 – 5 quarters. If the results are positive, VKTX share value could rise significantly, in our opinion.

*Healthcare/Biotechnology*

Ticker: **VKTX**  
Rating: **Buy**  
Price Target: **\$ 20.00**

#### Trading Data:

Last Price (11/17/2015)	\$ 5.12
52-Week High (5/5/2015)	\$ 10.23
52-Week Low (11/11/2015)	\$ 4.55
Market Cap. (MM)	\$ 50
Shares Out. (MM)	10

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-15E</b>	-1.40A	-1.07A	-0.53A	-0.45	-2.92	N.A.
<b>FY-14A</b>	-0.07	3.88	-3.01	-2.01	-5.23	N.A.
<b>FY-13A</b>	0.00	-20.39	-5.57	-0.33	-0.07	N.A.
<b>FY-12A</b>	NA	NA	NA	NA	-0.07	N.A.

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Source: Laidlaw & Company estimates

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## Anticipated milestones in 2015 and beyond

Product	Indication	Event	Timing	Importance
VK5211	Hip fracture	Report pre-clinical primate data at Society on Sarcopenia, Cachexia and Wasting Disorders (SCWD) meeting	Dec. 4-6, 2015	***
		Report Phase IIa study results	2H16	****
VK0214/VK2809	X-Linked Adrenoleukodystrophy (X-ALD)	Initiate pre-clinical animal model study	4Q15	***
		Report pre-clinical animal model study results	1H16	***
		Initiate Phase I POC study	2H16	***
		Potentially report Phase I study top-line results	2017	****
VK2809	Cholesterolemia / NASH	Potentially start Phase II study	4Q15	***
		Potentially complete Phase II study	2H16	***
		Potentially report Phase II study results	1H17	****

\*\*\*\* / \*\*\*\*\* Major catalyst event that could impact share price very significantly while \*\*\* event is more informative

Source: Laidlaw & Company and company presentation

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## Major Risks

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**Risks of clinical study failure could have a major impact on VKTX share value.** Despite promising aspects of the company's lead products, VK5211 in the post hip fracture surgery rehabilitation and thyroid- agonists (VK2809 / VK0214) in X-ALD, it remains too early to predict the safety and efficacy from the two upcoming Phase I and Phase II studies. Given that clinical validation or POC for these programs has not been established, it would be critical for these studies to demonstrate a positive outcome in order to increase the asset and shareholder value. Negative results of either clinical study could potentially impair their value and have a materially negative impact on shareholder value, especially since success of each study could illustrate the value of VK5211 in hip fracture rehabilitation and thyroid- agonists in X-ALD. Further, it remains too early to predict any potential future success of clinical trials should these programs further advance into next stage clinical stage development. In thyroid- agonists in X-ALD, although it is possible that the drug could reduce or eliminate VLCFA, it remains too early to forecast that the drug could slow and stop the progression of symptoms to provide clinical benefits.

**Product may not be approved or reach anticipated sales.** Although Viking's current pipeline products have exhibited the potential to generate positive clinical outcomes from current and future trials; it remains too early to project whether any of these products would be approved by regulatory agencies. Even if the products were to enter the market, sales could be significantly below projections due to the specific product label under approval, physician consensus for prescribing the drug, changes of treatment paradigms, entrance of competitors, and possibly the changes in pricing flexibility and payer reimbursement. A revenue outlook below expectations could also negatively affect VKTX shareholder value.

**Positive relationship with Ligand is important.** Given that Viking is substantially dependent on technologies and drug candidates licensed from Ligand for further development, it would be important for the company to maintain a positive relationship with Ligand. If Viking loses the right to license these technologies and drug candidates or the Master License Agreement with Ligand is terminated for any reason, VKTX's ability to develop existing and new drug candidates would be harmed.

**Additional financings could dilute shareholder value.** Although the company currently has ~\$23MM cash after recent IPO financing, VKTX could need more financial resources going forward if they want to expand and further develop its pipeline. Should the product not receive FDA approval, or product revenue does not reach expectations; the company might need to issue new equity to raise additional cash. Under such a scenario, the share value of existing shareholders could be diluted.

**Limited trading liquidity limits shareholder options.** Given VKTX shares only entered the public market recently; daily trading volume and name recognition are relatively modest. With relatively illiquid trading volume, shareholders wanting to increase or reduce their positions in a volatile stock market may face constraints.

Figure 1: Income Statement

## Viking Therapeutics – Income Statement

(\$',000)	2012	2013	2014	1Q15	2Q15	3Q15	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
<b>Revenue</b>														
Product revenue	0.0	0.0	0.0	-	-	-	-	0	0	0	0	88,989	297,528	626,498
Other revenue	0.2	0.0	0.0	-	-	-	-	0	0	0	0	0	0	0
Total revenue	0.2	0.0	0.0	-	-	-	-	0	0	0	0	88,989	297,528	626,498
Costs of goods												10,679	35,703	75,180
Gross sales												78,310	261,825	551,318
Research and development	(69)	(12)	(22,223)	(139)	(1,101)	(2,508)	(2,509)	(6,256)	(11,261)	(19,482)	(27,080)	(29,517)	(31,878)	(34,110)
General and administrative	(41)	(89)	(1,245)	(322)	(1,526)	(1,781)	(1,638)	(5,267)	(6,900)	(9,246)	(9,708)	(10,193)	(10,703)	(11,238)
Marketing and sales												(31,000)	(54,250)	(59,675)
<b>Total Operating Expenses</b>	(110)	(101)	(23,468)	(461)	(2,627)	4,288	(4,147)	(11,523)	(18,161)	(28,728)	(36,788)	(70,710)	(96,831)	(105,023)
<b>Operating Incomes (losses)</b>	(109)	(101)	(23,468)	(461)	(2,627)	4,288	(4,147)	(11,523)	(18,161)	(28,728)	(36,788)	18,279	200,697	521,475
Change in fair value of accrued license fees	0	0	(1,822)	4,961	4,421	0	0	9,382	0	0	0	0	0	0
Change in fair value of debt conversion features	0	21	(391)	83	546	(197)	100	532	(200)	(500)	(500)	(500)	(500)	(500)
Amortization of debt discount	0	18	558	172	241	(241)	(241)	(69)	480	0	0	0	0	0
Interest expense	1	6	71	35	30	(10)	(10)	44	22	0	0	0	0	0
Total other (income) expenses	1	45	(1,584)	5,250	5,238	(448)	(151)	9,889	302	(500)	(500)	(500)	(500)	(500)
Loss before tax	(111)	(146)	(21,884)	(5,711)	(7,865)	4,737	(3,996)	(21,413)	(18,463)	(28,228)	(36,288)	18,779	201,197	521,975
Tax	0	0	0	-	-	-	-	0	0	0	0	(6,948)	(74,443)	(193,131)
<b>Net Income (Loss)</b>	(111)	(146)	(21,884)	(5,711)	(7,865)	(4,737)	(3,996)	(21,413)	(18,463)	(28,228)	(36,288)	11,830	126,754	328,844
Net Income (Loss) Applicable to Common Shareholders	(111)	(146)	(21,884)	(5,711)	(7,865)	(4,729)	(3,996)	(21,413)	(18,463)	(28,228)	(36,288)	11,830	126,754	328,844
Net Earnings (Losses) Per Share—Basic	(\$0.07)	(\$0.07)	(\$5.23)	(\$1.40)	(\$1.07)	(\$0.53)	(\$0.45)	(\$2.92)	(\$1.43)	(\$1.89)	(\$2.14)	\$0.54	\$5.77	\$14.98
Net Earnings (Losses) Per Share—Diluted	(\$0.07)	(\$0.07)	(\$5.23)	(\$1.40)	(\$1.07)	(\$0.53)	(\$0.45)	(\$2.92)	(\$1.43)	(\$1.89)	(\$2.14)	\$0.54	\$5.77	\$14.98
Shares outstanding—basic	1,483	2,043	4,187	4,074	7,332	8,947	8,949	7,326	12,949	14,949	16,949	21,949	21,952	21,954
Shares outstanding—diluted	1,483	2,043	4,187	4,074	7,332	8,947	8,949	7,326	12,949	14,949	16,949	21,949	21,952	21,954
<b>Margin Analysis (% of Sales/Revenue)</b>														
Costs of goods												12%	12%	12%
R&D	-33433%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-33%	-11%	-5%
SG&A	-19791%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-11%	-4%	-2%
Operating Income (loss)	-53124%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	21%	67%	83%
Pretax	-537.9223	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	21%	68%	83%
Tax Rate										0%	37%	37%	37%	37%
Net Income	-53792%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	13%	43%	52%
<b>Financial Indicator Growth Analysis (YoY%)</b>														
Total Revenue	NA	-100%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	234%	111%
R&D	NA	-83%	191264%	178%	NA	NA	-89%	-72%	80%	73%	39%	9%	8%	7%
SG&A	NA	119%	1292%	102%	NA	NA	72%	323%	31%	34%	5%	5%	5%	5%
Marketing and sales					NA	NA							75%	10%
Operating Income (Losses)	NA	-8%	23118%	120%	NA	NA	-82%	-51%	58%	58%	28%	-150%	988%	160%
Pretax Income	NA	32%	14864%	2395%	NA	NA	-81%	-2%	-14%	53%	29%	-152%	971%	159%
Net Income	NA	32%	14864%	2395%	NA	NA	-81%	-2%	-14%	53%	29%	-133%	971%	159%
EPS	NA	-4%	7202%	1855%	NA	NA	-78%	-44%	-51%	32%	13%	-125%	971%	159%

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Source: Bloomberg LP; Company reports; Laidlaw &amp; Company estimates

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#### Rating and Price Target Change History



#### 3 Year Rating Change History

Date	Rating	Closing Price (\$)
06/08/2015	Buy (B)	8.02

#### 3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
06/08/2015	20.00	8.02

Source: Laidlaw & Company

Created by: Blue-Compass.net

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	71.88%	25.00%	6.25%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	3.13%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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